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Serial No. : 10/037,341
Filed : January 4, 2002
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REMARKS

Claims 90 and 91 were pending in the subject application. By this Amendment, Applicants amended claims 90 and 91.

Support for amended claim 90 can be found, *inter alia*, on page 8, lines 18-21; on page 29, lines 25-28; on page 81, line 31 to page 82, line 2; and on page 82, lines 20-23 of the subject application.

Support for amended claim 91 can be found, *inter alia*, on page 7, lines 28-30; on page 8, lines 1-7 and lines 18-21; on page 8, line 16 to page 9, line 9; on page 27, lines 17-20; on page 29, lines 25-28; on page 81, line 31 to page 82, line 2; and on page 82, lines 20-23 of the subject application.

Accordingly, Applicants maintain that this Amendment raises no issue of new matter, and respectfully request that this Amendment be entered. Upon entry of this Amendment, claims 90 and 91 will be pending and under examination.

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Rejection Under 35 U.S.C. § 112, First Paragraph

In the May 6, 2009 Office Action, the Examiner rejected pending claims 90 and 91 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention. To support this assertion, the Examiner cited the decision of the Court of Appeals of the Federal Circuit (hereinafter "the Federal Circuit") in *ARIAD Pharmaceuticals, Inc. et al. v. Eli Lilly and Company*, 560 F.3d 1366 (Fed. Cir. 2009).

Applicants' Response

Applicants respectfully traverse the rejection for at least the following reasons:

I. **ARIAD Decision Has Been Vacated**

Applicants note that on August 21, 2009, the Federal Circuit granted ARIAD's petition for rehearing en banc. This decision also vacated and rendered void the earlier ARIAD decision relied upon by the Examiner. The Examiner has been made aware of this fact in a Supplemental Information Disclosure Statement filed September 22, 2009 in connection with the subject application.

In the May 6, 2009 Office Action, the Examiner expressly stated that "the relevant criteria used for determining lack of written description for the '516 patent will be used to compare the instant claims 90 and 91 and applied accordingly. The instant application fails to meet the criteria set forth

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by the *Ariad* decision...." Since the *ARIAD* decision relied upon by the Examiner has been vacated, Applicants respectfully submit that the rejection of the pending claims based on the decision has been rendered moot.

II. 35 U.S.C. § 112, Second Paragraph, Does Not Have A
Written Description Requirement

Applicants further note that the Federal Circuit granted *ARIAD*'s petition for rehearing to address two issues relevant to the subject application:

- 1) whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement? and
- 2) if a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?

Applicants submit the relevant appeal brief and amicus briefs to the U.S. Patent and Trademark Office in a Supplemental Information Disclosure Statement herewith.

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Rejection Under 35 U.S.C. § 112, Second Paragraph

In the May 6, 2009 Office Action, the Examiner also rejected pending claims 90 and 91 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In the rejection, the Examiner indicated the following issues:

I. Antecedent Basis

In the rejection, the Examiner alleged that in each claim the antecedent basis for "the cell" in the phrase "contacting the cell" is unclear because it is unclear if such antecedent basis is found in the phrase "[a] method for reducing expression in a human cell of a gene", lines 1-2, or instead is found in the preamble phrase "in the cell" in line 5. The Examiner went on to state that it appears that the antecedent basis for "the cell" in one active method step is referring to the phrase "a human cell" in lines 1-2.

Applicants' Response

Applicants respectfully submit that the language of the pending claims is clear. By this Amendment, Applicants have further amended claims 90 and 91 to expressly recite "the human cell", thus making the antecedent basis unambiguously clear.

II. Claims Clearly Pointed Out The "Metes And Bounds" Of The Claimed Invention

The Examiner further alleged that it is unclear how the claim limitations correlate to "the cell" of the active method step. The Examiner asserted that one of ordinary skill in the art would not be able to determine the metes and bounds of

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Applicants inventions.

Applicants' Response

Applicants respectfully traverse. First, Applicants note that the Examiner did not provide any factual or legal support for asserting that one of ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention.

Moreover, Applicants respectfully submit that the amendments to claims 90 and 91 presented herein fully address the Examiner's rejection. In view of the specification's disclosure, one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention.

Accordingly, Applicants respectfully submit that the rejection of the pending claims under 35 U.S.C. § 112, second paragraph, should be withdrawn.

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Nonstatutory Obviousness-type Double Patenting Rejection

In the May 6, 2009 Office Action, the Examiner further alleged that the pending claims are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 9-17, 20-63, 88-94, 96-143, 146-176 and 192-203 of U.S. Patent No. 6,410,516. The Examiner noted that Applicants have previously indicated that a Terminal Disclaimer will be filed upon indication of allowable subject matter should the allowable subject matter so require.

Applicants' Response

In response, Applicants hereby maintain that such a Terminal Disclaimer will be filed upon indication of allowable subject matter should the allowable subject matter so require.

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Provisional Nonstatutory Obviousness-type Double Patenting

In the May 6, 2009 Office Action, the Examiner further alleged that the pending claims are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 89 of copending Application No. 10/037,415.

Applicants' Response

In response, Applicants note that the current rejection is provisional as the cited application is not patented or allowed. Applicants respectfully defer discussion of the provisional rejection until the double patenting rejections are the only rejections remaining in the present application. M.P.E.P. §804(I)(B).